

**FISH AND WILDLIFE SERVICE  
ADMINISTRATIVE PROCEDURE**

**Administrative Procedure**

**Part 202 The Federal Register**

**Chapter 2 Preparation**

**202 FW 2**

**2.1 What is the purpose of this chapter?** This chapter provides supplemental guidance for preparing rulemaking actions. The Departmental Manual at 318 DM provides extensive guidance on the requirements for drafting rules and Record of Compliance documents (ROCs).

**2.2 How does a program office decide if a rule is necessary or advisable?** To decide whether rulemaking is necessary or advisable, first determine whether adequate authority exists for us to publish a rule. If we have the authority, then ask yourself the following questions:

**A. Why should the Service publish this rule?** Consider why we need the regulation or what problem it will solve. Some reasons for rulemaking include:

- (1) A specific legislative requirement,
- (2) Program deficiencies identified as the result of an audit,
- (3) Chronic abuses or problems that need a remedy, or
- (4) A need to show the public that we will be consistent in the way that we administer our programs.

**B. Are there any alternatives to rulemaking that are feasible?** For the need you identified by asking the question above, consider the possible alternatives to rulemaking and whether or not they are feasible.

**2.3 What do you need to do before you begin drafting a rule?** Before drafting Federal Register documents, you should review 318 DM. You can find additional guidance at 1 CFR Parts 18, 21, 22, and 51. The Division of Policy and Directives Management (PDM) encourages program offices to consult with them for guidance before they begin drafting documents. PDM has copies of all documents referenced in Part 202. Executive Order (E.O.) 12866, Regulatory Planning and Review, requires that you develop specific planning documents before drafting a rulemaking document:

**A. Unified Agenda.** E.O. 12866 requires that we publish the Unified Agenda of Regulatory and Deregulatory Actions, a list of anticipated rulemaking actions for the following 12-month period.

- (1) PDM prepares the Service's portion of the Unified Agenda. PDM typically solicits data for the Unified Agenda from the program offices every February and August.
- (2) Program offices must update the data review forms PDM provides on all rulemaking actions we published in previous Unified Agendas.
- (3) Program offices must also alert PDM to new rulemaking actions that they anticipate publishing in some stage during the next 12 months.
- (4) PDM provides Regulation Identifier Numbers (RINs) for all rulemaking actions (see 202 FW 1.6).

**B. Regulatory Alert.** Program offices must:

- (1) Prepare a Regulatory Action Alert form. This Department-mandated form describes a rulemaking action, any possible controversy or sensitivity, and the anticipated publication date. It gives other Department of the Interior (DOI) bureaus information that can help them decide if they want to participate in the development of the rule.

**FISH AND WILDLIFE SERVICE  
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**Administrative Procedure**

**Part 202 The Federal Register**

**Chapter 2 Preparation**

**202 FW 2**

**(2)** Submit the form to PDM. PDM sends it to the DOI Office of the Executive Secretariat and Regulatory Affairs (OES) for circulation to the other bureaus. The form is available in 318 DM 2, or you can get it from PDM.

**C. OMB Regulatory Report.** E.O. 12866 also requires that we work with the Office of Management and Budget (OMB) to designate significance for all rulemaking actions.

**(1)** OMB reviews all rules that they designate as significant. We cannot publish a significant rule in the Federal Register until OMB has reviewed it. We use the following four criteria to make an initial determination about whether or not a rule is significant. OMB makes the final determination. Significant rules are those that may:

**(a)** Have an annual effect on the economy of \$100 million or more, or adversely affect in a material way the economy; a sector of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribal governments or communities;

**(b)** Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

**(c)** Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients of those programs; or

**(d)** Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in E.O. 12866.

**(2)** We provide our initial determinations of significance to OMB through quarterly reports of upcoming regulatory actions. PDM prepares the Service report and submits it to OES for incorporation into a single Departmental report. OES sends the DOI report to OMB.

**(3)** When PDM requests data for the OMB regulatory report, the program offices must provide the data in the table format requested. See Exhibit 1 for an example of OMB regulatory report data format. The data include:

**(a)** The title of the rulemaking action,

**(b)** A brief description (generally just a sentence or two),

**(c)** The designation of significance under E.O. 12866 (significant or not significant), and

**(d)** A point of contact and telephone number for more information.

**(4)** DOI sends the reports of upcoming regulatory actions to OMB on a quarterly basis: January 1, April 1, July 1, and October 1.

**(5)** OES sends the DOI regulatory reports to OMB just before the quarterly dates listed above. OMB has 10 working days to respond to the regulatory report. PDM then advises the program offices if OMB has changed any of the designations we have proposed. OMB generally designates rules as:

**(a)** Significant: OMB will formally review the rule using the procedures in E.O. 12866,

**(b)** Not significant but needs informal review: OMB will conduct an informal review, generally in 10 days or less, of the rule,

**FISH AND WILDLIFE SERVICE  
ADMINISTRATIVE PROCEDURE**

**Administrative Procedure**

**Part 202 The Federal Register**

**Chapter 2 Preparation**

**202 FW 2**

(c) Not significant and OMB will not review the rule, or

(d) Informational copy: OMB will not review the rule but wants us to send a copy to them at the same time we send the rule to the Office of the Federal Register for publication.

(6) The program offices must track OMB's designations. When drafting a significant rule, the program offices must include certain language in the preamble. The language is found in 318 DM 4, Appendix 2.

**2.4 What are the principles of regulation that a program office should consider before and during rulemaking?** Keep the following principles, from E.O. 12866, in mind before and during rulemaking:

**A.** Identify the problem you intend to solve through rulemaking and assess the significance of that problem.

**B.** Examine whether existing regulations (or other laws) have created or contributed to the problem that you intend to correct through the new regulation and whether we should modify those regulations or other laws to achieve the intended goal of the regulation more effectively.

**C.** Identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information that the public can use to make choices.

**D.** In setting priorities, consider the degree and nature of risks posed by various substances and activities within our jurisdiction.

**E.** Design the regulation in the most cost-effective manner to achieve the regulatory objectives. Consult the Department's Office of Policy Analysis and/or our Division of Economics for assistance. Consider:

(1) Incentives for innovation, consistency, and predictability;

(2) Enforcement and compliance costs to the government, regulated entities, and the public;

(3) Flexibility;

(4) Distributive impacts; and

(5) Equity.

**F.** Assess the costs and benefits of the intended regulation. Propose the regulation only when you determine that the benefits of the intended regulation justify its cost.

**G.** Base regulatory decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation.

**H.** Identify and assess alternative forms of regulation and, to the extent feasible, specify performance objectives rather than specifying the behavior or manner of compliance that regulated entities must adopt.

**I.** Whenever feasible, work with and for State, local, and tribal governmental entities by:

(1) Seeking their views before imposing regulatory requirements that might significantly or uniquely affect them.

FISH AND WILDLIFE SERVICE  
ADMINISTRATIVE PROCEDURE

**Administrative Procedure**

**Part 202 The Federal Register**

**Chapter 2 Preparation**

**202 FW 2**

(2) Assessing the effects of the regulation on their governments, including the availability of resources to carry out any mandates.

(3) Minimizing the burdens that uniquely or significantly affect them, consistent with achieving regulatory objectives.

(4) Harmonizing our regulatory actions with related State, local, and tribal regulatory functions.

J. Avoid regulations that are inconsistent or incompatible with, or duplicative of, other Federal regulations.

K. Tailor regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives. Take into account, among other things and to the extent practicable, the costs of cumulative regulations.

L. Draft regulations so that they are simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation because of the uncertainty.

**2.5 When does the program office prepare a Record of Compliance (ROC)?**

A. When you are drafting a rule, you should prepare a draft ROC. (See 202 FW 1.6 for the definition of a ROC and 318 DM 3 for detailed information on how to prepare one.)

B. When you complete the ROC, and 15 days before publication of the rule, you must e-mail your ROC to the following offices (visit PDM's Contact Information webpage for the e-mail addresses):

(1) OES,

(2) The Office of Policy Analysis (PPA),

(3) The Office of Small and Disadvantaged Business Utilization (OSDBU), and

(4) The Small Business Administration (SBA).

**2.6 Is it possible for a program office to draft a rule that is not included in the Unified Agenda or the OMB regulatory report?** Yes; however, you should alert PDM about the rule as soon as possible so that it can notify OMB.

  
DEPUTY  
DIRECTOR

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